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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,452	06/09/2005	Yixian Qin	788-20-PCT-US (R7450)	8706

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THE FARRELL LAW FIRM, P.C.
290 Broadhollow Road
Suite 210E
Melville, NY 11747

EXAMINER	
BOR, HELENE CATHERINE	
ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,452	QIN ET AL.	
	Examiner	Art Unit	
	HELENE BOR	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 1, 2, 4-5, 10, 21, 23, 26 & 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Laugier et al. (Laugier, P. et al., "Ultrasound images of the os calcis: a new method of assessment of bone status," *Ultrasonics Symposium, 1993. Proceedings., IEEE 1993* , vol., no., pp.989-992 vol.2, 31 Oct-3 Nov 1993; enclosed herein).

Claim 1, 2, 4-5, 10, 21, 23, 26 & 28-29: Laugier teaches a system for determining at least one bone property of a bone sample at at least one point (Page 990, Left Column). Laugier teaches each transducer in turn acts a transmitter/receiver (Page 990, Left Column). Laugier teaches both transducers being confocal [focused] transducers (Abstract & 991, Left Column). Laugier teaches the sample was submerged in water between the two transducers (Page 990, Left Column) such that the confocal [focus] point of the transducers are located at the at least one point in the bone sample (Page 989, Right Column). Laugier teaches a processor [IBM PC, ultrasonic pulser-receiver, amplifier, digitizer system] that initiates an ultrasonic signal from the transmitting transducers that is transmitted through the at least one point of the bone sample when positioned between the transducers and received by the receiving transducer, the processor receiving a signal reflecting one or more measures of the received ultrasonic signal, the processor determining at least one ultrasonic parameter for the at least one

point of the bone sample based upon the transmitted and received ultrasonic signals, the processor further determining the at least one bone property at the point of the sample based upon the at least one ultrasonic parameter (Page 989, Right Column). Laugier teaches wherein the at least one ultrasonic parameter determined for the at least one point of the sample are ultrasonic velocity (UV) [SOS] and a measure of ultrasonic attenuation (UA) [BUA] (Abstract). Laugier teaches wherein the measure of UA is one selected from the group of broadband ultrasonic attenuation (BUA) (Abstract). Laugier teaches scanning the entire bone and driving the transducers with step motors for alignment (Page 990, Left Column & Page 992, Left Column). Laugier teaches using bone samples from fresh female cadavers, however, Laugier disclosures the system for scanning the entire os calcis in vitro (Page 989, Right Column).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 5-9, 11-20, 24 & 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugier et al. as applied to claims 1, 2, 4-5, 10, 21, 23, 26 & 28-29 above, and further in view of Mazess (US Patent No. 5,840,029).

Claim 5-9, 24 & 26: Laugier teaches scanning the entire bone (Page 992, Left Column) at 1 mm intervals, however, Laugier teaches step motor with finer step motion of 1/100 mm (Page 990, Left Column). Laugier teaches scanning in the x and y directions (Page 990, Left Column). Laugier fails to teach the z direction. However, Mazess teaches using the system for three dimensional grid (x, y, and z plane) and

moving the transmitting and receiving transducers in three dimensions (Col. 27, Line 41-44 & Col. 27, Line 61 – Col. 28, Line 6) in order provide a much more precise bone characterization (Col. 28, Line 16-18). Mazess teaches the three dimensional scanning stage (Col. 27, Line 40-44) wherein it is able of discrete scans, continuous scans and other methods of use that the clinician desires can be selected by a selectable switch (Col. 6, Line 32-67). It would have been obvious to one of ordinary skill in the art of modify the system of Laugier to include the z direction scan as taught by Mazess (Col. 27, Line 41-44 & Col. 27, Line 61 – Col. 28, Line 6) in order provide a much more precise bone characterization (Col. 28, Line 16-18) .

Claim 11: Laugier fails to teach the details regarding the calculations made for UV. However, Mazess teaches a system wherein ultrasound velocity (Abstract) at the at least one point of the sample is calculated by the processor (Figure 4, Element 41). Mazess teaches using the time delay, the thickness of the bone and the velocity of the ultrasound in the medium (Col. 12, Line 65-67 & Col. 19, Line 17-26 & 50-58) to provide spatially sensitive information about bone quality (Col. 2, Line 47-49). It would have been obvious to one of ordinary skill in the art to modify the system of Laugier to include the calculations as taught by Mazess to provide spatially sensitive information about bone quality (Col. 2, Line 47-49).

Claim 12, 14, 16 & 19: Mazess goes into detail regarding the applicant defined ATT, although Mazess does not use the term ATT. Mazess states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). Mazess teaches a system wherein the ATT at the at least one point (x,y,z)

of the sample is calculated by the processor from the energy of the received ultrasound signal as passed through the bone sample and the energy of a reference ultrasound signal received without the sample positioned between the transducers (Col. 9, Line 5-39). Mazess states that ultrasound attenuation is dependent on bone mineral density and the integrity being tested (Col. 9, Line 26-54). In addition, Mazess teaches a system capable of determining stiffness (Col. 27, Line 38-39). Mazess does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39).

Claim 13: Mazess teaches using the system for three dimensional grid (x, y, and z plane) (Col. 27, Line 40-44). Mazess teaches a system where the BUA at the at least one point (x,y,z) of the sample is calculated by the processor (Figure 6, Element 38) as the slope of the linear section of the ultrasound attenuation coefficient function, $UAC_{(x,y,z)}$ (f), where $UAC_{(x,y,z)}$ (f) is calculated from the fast fourier transform (FFT) of frequency f (as a function of time) for the received ultrasound signal f_{bone} (t) as passed through the bone sample and a reference (Col. 11, Line 10-16). Ultrasound signal f_{ref} (t) received without the sample positioned between the transducers in accordance with the equation (Col. 9, Line 8-10).

Claim 15 & 27: Mazess teaches where at least one bone property determined at the at least one point is bone mineral density (BMD) (Figure 26, Element 418 & Col. 28, Line 30-39).

Claim 17 & 20: Mazess teaches using linear regression constants predetermined by conducting a regression analysis between measurements of BUA on bone specimens

and BMD measurements on the bone specimens using conventional analysis (Col. 11, Line 9-16). In addition, Mazess teaches the use of UV (Col. 19, Line 17-49) and ATT (Col. 9, Line 26-54) for determining the BMD.

Claim 18: Mazess teaches a system wherein the at least one bone property determined at the at least one point is Stiffness (Col. 27, Line 30-40). The applicant defines Stiffness as "From the tissue level regions of bone that experience relatively high stiffness tend more towards cortical bone. Regions of bone experiencing low Stiffness tend to be more trabecular" (Page 3). From the applicant's admission, stiffness is related to the amount of either the cortical or trabecular bone. While Mazess does not explicitly use the word stiffness, Mazess does teach a system capable of measuring both the trabecular and cortical bone and both reading providing distant data about the bone (Col. 27, Line 38-39). Mazess also cites an article by Lees stating "[V]arious studies involving attenuation and speed of sound measurements in both cortical and spongy (cancellous or trabecular) bone….The transit time of an acoustic signal through a bone member therefore are proportional to the bone density" (Col. 2, Line 3-12).

5. Claim 3, 4 & 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugier et al. as applied to claims 1, 2, 4-5, 10, 21, 23, 26 & 28-29 above, and further in view of Kantorovich (US Patent No. 7,112,173).

Claim 3, 4 & 22: Laugier teaches using frequencies within the 200 to 600 kilohHertz range (Page 989, Right Column) but fails to teach higher frequencies. Laugier also teaches a resolution of 4 or 5 mm (*Abstract*, Page 989) but fails to teach a resolution approximately 0.5 mm. However, Kantorovich teaches a system wherein the

transmitting transducer emits ultrasonic signals at a frequency on the order of tens of megahertz [10 MHz] (Col. 21, Line 43-50) in order to have higher spatial resolution better than 1 mm (Col. 21, Line 43-50). It would have been obvious to one of ordinary skill in the art to modify the system of Laugier to include the higher frequency range and resolution of Kantorovich in order to have higher spatial resolution better than 1 mm (Col. 21, Line 43-50).

Response to Arguments

6. Applicant's arguments with respect to claim 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELENE BOR whose telephone number is (571)272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768